

Vitamin D screening in patients with inflammatory bowel disease

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Feasibility and Pilot studies

This is a definition that has been agreed by the Efficacy and Mechanism Evaluation (EME), Public Health Research (PHR), Health Technology Assessment (HTA) and Research for Patient Benefit (RfPB) Programmes.

We expect that when pilot or feasibility studies are proposed by applicants, or specified in commissioning briefs, a clear route of progression criteria to the substantive study will be described. Listing clear progression criteria will apply whether the brief or proposal describes just the preliminary study or both together. Whether preliminary and main studies are funded together or separately may be decided on practical grounds.

Feasibility studies

Feasibility Studies are pieces of research done before a main study in order to answer the question “Can this study be done?”. They are used to estimate important parameters that are needed to design the main study. For instance:

- standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
- willingness of participants to be randomised;
- willingness of clinicians to recruit participants;
- number of eligible patients; carers or other appropriate participants;
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- availability of data needed or the usefulness and limitations of a particular database; and
- time needed to collect and analyse data.

Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study.

If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

Pilot studies

Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects, including an assessment of the primary outcome. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.

Feasibility and pilot studies: which programme should I apply to?

There are a number of NIHR programmes which will fund feasibility and pilot studies. There are no strict rules about which programme funds which feasibility or pilot study and it is for applicants to choose the most appropriate in the context of the guidance on applicability provided on the webpages for each programme. Nevertheless, in choosing you might like to consider the following:

1. Is the programme appropriate in terms of geography and grant size (RfPB funding, for example, can only be accessed through NHS bodies and other providers of NHS services in England and has a maximum grant size of £350,000)?
2. Can a robust case be made for the plausibility of the intervention and clinical importance of any subsequent full trial? If there is good proof of concept and/or efficacy data available and there is a clear plan to explore the intervention further in a large clinical trial, then HTA or EME might be considered the latter in particular if there are substantial mechanistic elements and laboratory support involved in the project. On the other hand, if the feasibility or pilot study is for a potential trial which might be viewed as more speculative, with no clear plan for a large trial in the very near future, or in which there seems a high risk that the pilot/feasibility study is likely to demonstrate that a full trial is not possible, then the smaller sums that RfPB provide might be seen as more appropriate.

Note that feasibility and pilot studies should be distinguished from Phase II trials, in which some sort of evidence for efficacy, often in a surrogate marker, is sought prior to embarking on a full Phase III trial: EME might be the most appropriate funding stream for these if there

is strong scientific interest in the question, and RfPB if there is a clear potential trajectory into patient benefit.

The PHR Programme also funds feasibility and pilot studies within its remit of evaluating public health interventions delivered outside the NHS.

RfPB

Guidance on applying for feasibility studies

Clinical trials are expensive and the chances of successful completion are improved if it can be shown beforehand that key elements (such as the ability to recruit patients) are feasible before the main study starts. The RfPB Programme will therefore fund such feasibility studies which are investigations carried out before a main study in order to answer the question “Can this study be done?”. The research plan for a feasibility study should therefore contain a brief outline of the proposed main study and a list of the ‘uncertain’ important parameters that are needed to design the main study, as described below.

The Research Plan section of the application form should include:

1. A brief outline of the intended main trial.

Some of these details will of course depend on the results of the proposed feasibility research but a key part of evaluating the value of a feasibility study is whether or not a full trial is likely to get funded. You should therefore briefly describe as far as you can what the main trial would look like. This might include (if they are known), whether an individual patient randomised or cluster trial, the number of arms, the inclusion criteria, the nature of the intervention and of the comparator in the control group, the primary endpoint, and the possible range of clinical sites from which patients would be recruited.

2. A list of the parameters which the feasibility study intends to clarify or estimate.

These may include:

- the number of eligible patients, carers or other appropriate participants;
- an exploration of different methods of identifying/recruiting patients;
- the willingness of clinicians to recruit and randomise participants;
- the willingness of participants to be randomised;
- the practicality of delivering the intervention(s) in the proposed setting(s);
- variation in use or delivery of the intervention in each setting;
- acceptability of the intervention to the users;
- standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc;
- availability of data needed or the usefulness and limitations of a particular database;
- the time needed to collect and analyse data;

- exploring the opportunities for PPI (patient and public involvement) in the research design and its subsequent conduct.

In effect the research plan should describe which parameters are to be estimated and how these will be investigated.

3. A feasibility study does not necessarily need to include the following:

- a randomised design: the design will be determined by how it is proposed to reduce the uncertainty in the parameters described above
- an evaluation of the outcome of interest: that is left to the main study
- a primary outcome: if a feasibility study involves carrying out a small randomised controlled trial it is for the purpose of evaluating/testing trial processes not the intervention
- the usual sort of power calculation: the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision ³.

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